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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,051	07/23/2001	Weenna Bucay-Couto	01-089	3728

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EXAMINER

SERKE, CATHERINE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/911,051	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner Catherine Serke	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-20 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12 and 21-29 is/are rejected.
- 7) ☒ Claim(s) 9, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "said antiseptic agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 10-11, 21-22, 25-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanes et al (US Pat# 5,855,913).

Hanes discloses particles for incorporating surfactants for pulmonary drug delivery that includes a reservoir comprising a polymer matrix and an antimicrobial agent disposed within the polymer matrix. The polymer matrix is timed release (long-term) for administration of the antimicrobial agent (antibiotic or antiseptic) from the polymer matrix (7:22-25). A biosurfactant (surfactin) is imbibed or ionically or covalently attached to an outer surface of the reservoir (see

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5:16-23). The method of constructing steps are considered inherent since those steps must be carried out in order to make the particles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes.

Hanes meets the claim limitations as described above but fails to the antimicrobial agent being selected from the agents in claim 9 or iodine.

At the time of the invention, it would have been obvious to use any of the above agents since they are equivalents in the art. The motivation would have been to enhance the ability of the device to prevent infection.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes.

Hanes meets the claim limitations as described above but fails to disclose the method step of co-casting or co-extruding the agent with the polymer.

At the time of the invention, it would have been obvious to utilize the method steps of co-casting or co-extruding since these are equivalent processing steps in the art. The motivation for making the substitution would have been in order to have alternative processing capabilities.

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Claims 5-6 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes in view of Vacheethasane.

Hanes meets the claim limitations as described above but fails to have a surfactant that is a surfactant polymer.

Vacheethasane discloses surfactant polymers designed to suppress bacterial adhesion on biomaterials. The surfactant polymers include a polymer as claimed in claim 6.

At the time of the invention it would have been obvious to incorporate the surfactant polymer of Vacheethasane into the invention of Hanes to provide an outer surface with enhanced ability to prevent bacterial adhesion.

Allowable Subject Matter

Claims 15-20 are allowed.

Claims 8 and 13-14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat#s 5,344,411; 5,626,862; 5,874,064; 5,985,309; 5,156,164; and RE37,053 all disclose analogous inventions in the art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *CS.*
September 13, 2002

Brian L. Casler
BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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